(54) Title: EXTERNAL FIXATION DEVICE WITH COMPOSITE RINGS

(57) Abstract

An improved external fixation device composed of a plurality of fixation rings, multiple tie rods, and pin holders which cooperate to immobilize a bone fracture. An improved composite fixation ring having a core of a resin matrix reinforced with fibers is covered with a braided sleeve with resin impregnating the sleeve and the core.
FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Code</th>
<th>Name</th>
<th>Code</th>
<th>Name</th>
<th>Code</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>AM</td>
<td>Armenia</td>
<td>GB</td>
<td>United Kingdom</td>
<td>MW</td>
<td>Malawi</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AT</td>
<td>Austria</td>
<td>GE</td>
<td>Georgia</td>
<td>MG</td>
<td>Madagascar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AU</td>
<td>Australia</td>
<td>GN</td>
<td>Guinea</td>
<td>ML</td>
<td>Mali</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BB</td>
<td>Barbados</td>
<td>GR</td>
<td>Greece</td>
<td>MN</td>
<td>Mongolia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BE</td>
<td>Belgium</td>
<td>HU</td>
<td>Hungary</td>
<td>MR</td>
<td>Mauritania</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BF</td>
<td>Burkina Faso</td>
<td>IE</td>
<td>Ireland</td>
<td>NZ</td>
<td>New Zealand</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BG</td>
<td>Bulgaria</td>
<td>IT</td>
<td>Italy</td>
<td>NL</td>
<td>Netherlands</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BJ</td>
<td>Benin</td>
<td>JP</td>
<td>Japan</td>
<td>NO</td>
<td>Norway</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BR</td>
<td>Brazil</td>
<td>KE</td>
<td>Kenya</td>
<td>NZ</td>
<td>New Zealand</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BY</td>
<td>Belarus</td>
<td>KG</td>
<td>Kyrgyzstan</td>
<td>PL</td>
<td>Poland</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CA</td>
<td>Canada</td>
<td>KP</td>
<td>Democratic People's Republic of Korea</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CF</td>
<td>Central African Republic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CG</td>
<td>Congo</td>
<td>KR</td>
<td>Republic of Korea</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CH</td>
<td>Switzerland</td>
<td>KZ</td>
<td>Kazakhstan</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CI</td>
<td>Côte d'Ivoire</td>
<td>LI</td>
<td>Liechtenstein</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CM</td>
<td>Cameroon</td>
<td>LK</td>
<td>Sri Lanka</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CN</td>
<td>China</td>
<td>LR</td>
<td>Liberia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CS</td>
<td>Czechoslovakia</td>
<td>LT</td>
<td>Lithuania</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CZ</td>
<td>Czech Republic</td>
<td>LU</td>
<td>Luxembourg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DE</td>
<td>Germany</td>
<td>LV</td>
<td>Latvia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DK</td>
<td>Denmark</td>
<td>MC</td>
<td>Monaco</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EE</td>
<td>Estonia</td>
<td>MD</td>
<td>Republic of Moldova</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ES</td>
<td>Spain</td>
<td>MG</td>
<td>Madagascar</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FI</td>
<td>Finland</td>
<td>ML</td>
<td>Mali</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FR</td>
<td>France</td>
<td>MN</td>
<td>Mongolia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GA</td>
<td>Gabon</td>
<td>MR</td>
<td>Mauritania</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MX</td>
<td>Mexico</td>
<td>NE</td>
<td>Niger</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NL</td>
<td>Netherlands</td>
<td>NO</td>
<td>Norway</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RO</td>
<td>Romania</td>
<td>RJ</td>
<td>Russian Federation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RU</td>
<td>Russian Federation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>Sudan</td>
<td>SG</td>
<td>Singapore</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SE</td>
<td>Sweden</td>
<td>SI</td>
<td>Slovenia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SK</td>
<td>Slovakia</td>
<td>SN</td>
<td>Senegal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SN</td>
<td>Senegal</td>
<td>SZ</td>
<td>Swaziland</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TD</td>
<td>Chad</td>
<td>TG</td>
<td>Togo</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TJ</td>
<td>Tajikistan</td>
<td>TT</td>
<td>Trinidad and Tobago</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UA</td>
<td>Ukraine</td>
<td>UG</td>
<td>Uganda</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>US</td>
<td>United States of America</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UZ</td>
<td>Uzbekistan</td>
<td>VN</td>
<td>Viet Nam</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
BACKGROUND OF THE INVENTION:

The present invention relates to fiber-reinforced composite structures having improved performance under shear, bending, and torsional stresses and a process for making fiber-reinforced composite structures. The composite structures are useful in a wide range of applications. They are especially useful as external fixation devices.

External fixation methods for treating bone fractures are well-known in the art, including the use of a number of curved rings or curved partial rings that are spaced apart and structurally connected using a plurality of tie rods. Transversely extending pins or wires are attached to the rings and extended from the rings and into the bones so that the frame and transverse pins support and/or load the bone tissue in a desired manner. Such methods are described in Fischer U.S. Patent No. 4,308,863 and Jamison et al. U.S. Patent No. 5,062,844.

External fixation ring systems are commercially available and utilize either metal or composite rings. Composite rings that are transparent to x-rays are desirable as they do not interfere with evaluation of medical radiographs. In addition, composite rings are lighter than comparable metal rings, resulting in improved patient comfort.

The above-referenced Fischer Patent describes partial metal rings having an I-beam cross-section resulting in high strength with minimum weight. Although I-beam structures generally make efficient use of materials by using the flange sections to resist bending forces, they generally provide more limited resistance to torsional forces.
In use, external fixation rings are subjected to shear, torsional, and bending forces. External fixation rings in the form of the fiber-reinforced composite structures of the current invention provide an improved balance of mechanical properties for improved performance under combined bending, shear, and torsional forces.

**Brief Description of the Drawings:**

Fig. 1 is a perspective view of an external fixation device installed on a fractured bone illustrating the external fixation rings of this invention.

Fig. 2 is an exploded perspective view partially in section of an external fixation ring of this invention.

Fig. 3 is a plan view of fixation rings of 240 degrees and 120 degrees angular lengths connected by connecting links.

Figs. 4A-4G illustrate a preferred process for making the fixation ring of this invention.

**Detailed Description of the Preferred Embodiment:**

The embodiment chosen for purposes of illustration is shown in Fig. 1 to include an external fixation device 10 composed of arcuate fixation rings 12 and 14, which are disposed about a fractured bone 16. The fixation rings 12 and 14 have an I-beam cross-section composed of a central web portion 18 and a pair of flanges 20. A plurality of holes 22 are formed and symmetrically spaced in the web portion. When installed upon fractured bone 16, a plurality of tie rods 24 pass through some of the holes 22 and are attached to rings 12 and 14 by fasteners 26 and 28.

Pin holders 30 and 32 are fastened at various locations on rings 12 and 14 and mount pins 34 and 36, which pass through the bone 16.
As best shown in Fig. 2, a fixation ring 12 has a core 13 formed of unidirectional fibers 21 in the flanges 20 and a plurality of layers 23 of unidirectional fibers in the web and a braided sleeve 25 formed about the core 13. The sleeve 25 is bound to the core 13 by resin, which impregnates the fiber of the core and the sleeve. The ring has a longitudinal axis designated 12\(\Delta\).

The unidirectional fibers 21 are aligned along the curved flanges 20, approximately parallel to the longitudinal axis 12\(\Delta\) and the layers 23 which make up the web core. Use of unidirectional fibers in the flanges 20 of the core results in improved resistance to bending forces in the final composite. Preferably, the unidirectional fibers 21 are oriented between 0 and about \(\pm 15\) degrees relative to the longitudinal axis of the core and the layers of the web of the core.

The web portion of the core is preferably reinforced with layers 23 of fibers oriented roughly parallel (between zero and about \(\pm 15\) degrees) to unidirectional fibers 21 and between approximately \(\pm 45\) degrees \(\pm 15\) degrees relative to a tangent to the longitudinal axis of the core, more preferably, between approximately \(\pm 45\) degrees \(\pm 5\) degrees, most preferably, approximately \(\pm 45\) degrees. This provides optimum resistance to shear stresses, which are generally greatest in the interior of the core. Preferably, the fiber orientation in the interior of the core is symmetric about the cross-sectional center-line 12\(\Delta\) and balanced in the positive and negative directions.

In order to improve the overall resistance of the composite ring to torsional forces and delamination within the core, a layer of fiber material is applied to the exterior surface of the inner core (e.g., braided sleeve 25). The fiber material is applied such that it conforms to the outer shape of the core and is oriented at between approximately \(\pm 45\) degrees \(\pm 15\)
degrees relative to the tangent of the longitudinal axis through the centroid of the ring or core, more preferably, between approximately ± 45 degrees ± 5 degrees, most preferably, approximately ± 45 degrees.

The term relative to the tangent of the longitudinal axis through the centroid of the ring or core means that for a particular cross-section, when XYZ coordinate axes at the centroid of the cross-section are drawn and the cross-section lies in the X-Y plane and Z is perpendicular to the X-Y plane, Z is the tangent to the longitudinal axis for that cross-section. All angles (for that cross-section) are measured relative to the Z axis. For horizontal surfaces, the angles are measured in the Y-Z plane and for vertical surfaces, angles are measured in the X-Z plane.

A wide range of fibers and polymeric matrices may be used to form the composite rings of the current invention. For end-uses such as external fixation devices where high strength and stiffness are required, carbon-fiber reinforced epoxy resins are preferred. Other fibers including aramide, glass, or nylon may be also used. Preferably, continuous filament reinforcing fibers are used. Thermoset or thermoplastic matrices may be used, including polyester, nylon, or bismaleimide resins. Preferably, the composite device comprises approximately 30-70 vol% fiber and 70-30 vol% resin. More preferably, the composite comprises approximately 50-70 vol% fiber, most preferably, approximately 65 vol% fiber.

External fixation rings may be formed from the composite rings of the current invention in a variety of diameters, lengths, and cross-section dimensions. For rings having I-beam cross-sections, increasing the thickness of the flange in general increases the bending strength; shear strength may be increased by increasing the thickness of the web. The external fixation devices may be formed as partial
rings, for example, as 120 degrees (1/3 ring), 240
degrees (2/3 ring), 180 degrees (1/2 ring), or full
rings. External fixation rings generally include a
plurality of holes 22 symmetrically spaced along the
length of the arcuate frame. The apertures may be
drilled into the part during final machining.

As shown in Fig. 3, partial ring segments 30
and 32 may be joined together by the use of connecting
links 17. The connecting link 17 may include bosses
(not shown) to engage the ring between the flange
sections for rings having I-beams cross-sections. The
link is attached to the ring using screws (not shown)
through holes 22 at the ends of each ring section.

Figs. 4A-4G illustrate a process for forming
an arcuate fiber-reinforced composite I-beam ring 12
according to the current invention. An arcuate fiber-
reinforced resin I-beam core is formed, covered with a
fiber material, and enclosed in a mold shaped to
conform to the shape of the fiber-covered core. Resin
is then injected into the closed mold under pressure to
impregnate the fiber material and bond it to the core.
Injecting resin under pressure into the unimpregnated
fiber material surrounding the core results in isobaric
conditions during injection and more uniform properties
in the final part than would be achieved by applying
prepreg material to the core and consolidating under
heat and pressure with no resin injection.

Figs. 4A-4E illustrate steps in forming the
arcuate fiber-reinforced composite core having an I-
beam cross-section. Unidirectional fiber prepreg
material (containing unidirectional fibers and resin)
may be placed in grooves in each half of a mold, as
shown in cross-section for one half of the mold in Fig.
4B. To facilitate lay-up of the unidirectional fibers
21, unidirectional fiber prepreg sheet material may be
cut into strips 40 with the fibers running along the
long dimension of each strip. The strips may then be
folded along the direction of the unidirectional fibers
21 several times to provide unidirectional "noodles" 42. In Fig. 4A, the strips have been folded in half and then in thirds to form a noodle structure. The noodles are placed in grooves which run along the inner and outer edges of each side of the mold 30 and will ultimately form the flange section 20 of the core 13. Alternatively, layers of unidirectional tow that has been impregnated with resin may be laid into the groove. However, the use of prepreg sheet material assures more reproducible lay-up of fibers and better control of fiber orientation in the final part.

A convenient way to form the web portion of the core is to cut a plain weave prepreg fabric at 45 degrees to the fiber axes. Plain weave is preferred because there are equal amounts of fiber in the warp and fill directions. Other weaves may be used which do not contain balanced fiber ends in the warp and fill directions. The fiber ends in the + and - directions may then be balanced by flipping the fabric over in alternating layers or by cutting alternating layers at 90 degrees from each other in the original fabric. Alternatively, unidirectional fiber prepreg sheet may be used with alternating layers of fiber oriented at approximately 45 degrees in the + and - directions.

Woven fabrics are generally more convenient when constructing parts having substantial thickness as they are generally available in greater thicknesses and contain more fiber ends than commercially available unidirectional ply materials. The undulations present in woven fabric can result in parts having higher toughness as the undulations may resist the propagation of cracks. However, the undulations may also reduce the strength and stiffness of the final part.

The cut-to-size rectangular prepreg strips or layers 23 are placed into each of the mold halves overlaying the unidirectional noodles at the inner and outer edges as shown in Fig. 4C. To facilitate working the fabric strips into the shape of curved molds, the
mold may be warmed during placement of the fabric plies. To increase the thickness of the web, the layers could be also placed in between the noodles.

After lay-up of the noodles of unidirectional fibers 21 and fabric layers 23, the mold is closed as shown in Fig. 4D and heated under pressure to sufficient temperature and pressure to consolidate the core 13. The consolidated core 13 (Fig. 4E) is then removed from the mold, and may be machined to the appropriate dimensions and the surface sanded to remove excess resin and mold lines. Preferably, the surface is sanded to provide an even matted finish with no visible fiber fraying. This is conveniently done using a sandblaster, taking care not to oversand.

As shown in Fig. 4F, a fiber material is then applied to the outer surface of the prepared inner core. This may be done by pulling one or more ± 45 degrees braided sleeves 25 having a circumference that is approximately equal to that of the composite I-beam over the outer surface of the core. By using a braid having a circumference that is approximately equal to that of the core, the fibers in the braid will be oriented approximately ± 45 degrees relative to the tangent to the longitudinal axis of the core. The initial braid angle is preferably chosen such that the final braid angle in the composite part is approximately ± 45 degrees. Depending on the weight of braid used, a single braided sleeve may be used, or multiple sleeves may be applied to achieve the desired final part volume. In general, the number of filaments in the tow and the pick count should be chosen to reduce the number of undulations in the fabric for a desired weight. Braided fabrics are especially useful as the outer surface fiber material because they can be easily worked into and around complex shapes such as I-beams and eliminate seams in the outer covering fibrous material.
Alternatively, the fiber material may be applied to the inner core by overbraiding or overwinding the part with a tow of the desired fiber. Tow may be wound on the part, alternating layers of approximately ± 45 degrees and - 45 degrees relative to the tangent of the arc of the core. This approach is more readily applied to simple shapes such as rectangular, square, or circular cross-sections.

After application of the fiber material to the outer surface of the inner core, the part is placed into an injection mold 45 (Fig. 4G) shaped to conform to the shape of the covered inner core. The mold is closed, heated, and resin injected under pressure to impregnate the braided preform to form a composite article.

Although composite structures having I-beam cross-sections are disclosed, it is to be understood that the advantages of this invention may be achieved using other cross-sections, such as rectangular and square. For example, in a curved flat ring, ± 45 degree ± 15 degree unidirectional sheet or woven fabric prepreg may be used to reinforce the interior of the ring and unidirectional sheet or tow may be used to reinforce the inner and outer edges of the core component of the ring. The fibrous materials may be a braided sleeve as described above. Alternately, flat rings may be overwound with layers of ± 45 degree ± 15 degree tow.
What is Claimed is:

1. A method for making a composite article comprising: forming a core of a resin matrix reinforced with fibers; covering said core with a fiber material; enclosing said core covered with fiber material in a mold shaped to conform to said article; and injecting a polymeric resin under pressure into said mold to force resin through said fiber material.

2. A method according to claim 1, wherein said core comprises an arcuate structure having curved flanges and a longitudinal axis, said forming step including laying up of unidirectional fiber-resin prepreg material within the curved flanges wherein said unidirectional fiber-resin prepreg material is aligned generally parallel to the longitudinal axis of the core, and laying up layers of woven prepreg fabric fibers or unidirectional fiber prepreg sheet wherein said layers are oriented generally parallel to the unidirectional fiber-resin prepreg material and the fibers within layers are between about ±45 degrees ±15 degrees relative to the longitudinal axis of the core, and heating under pressure to consolidate the core.

3. A method according to claim 2, wherein said fiber material comprises a braided sleeve comprising continuous filament tow and wherein said covering step comprises inserting said core into said braided sleeve.

4. A method according to claim 1, wherein said fiber material comprises continuous filament tow and wherein said covering step comprises overbraiding or overwinding the core with said continuous filament tow.

5. A method according to claim 3 or 4, wherein the continuous filament tow is oriented at between about ±45 degrees ±15 degrees relative to a longitudinal axis of the core.
6. A unitary composite article comprising:
a core of a resin matrix reinforced with fibers; a
fiber material covering said core; and a resin
impregnating said fiber material.

7. The unitary composite article of claim 6, wherein the core fibers are oriented in transverse
and non-transverse directions with respect to the longitudinal axis of the article.

8. The unitary structure of claim 6 or
claim 7, wherein said fiber material covering said core
is a braided sleeve.

9. The unitary composite article of claim 6, wherein said core comprises a curved I-beam cross-
section having flanges and a web and a longitudinal
axis said core fibers include unidirectional fibers
within said flanges and further include layers of
material forming said web, said unidirectional fibers
being aligned generally parallel to the longitudinal
axis of the core and to said layers of material, and
wherein said layers of material include fibers, said
fibers within said layer being oriented between about ±
45 degrees ± 15 degrees relative to the longitudinal
axis of the core, the angles being balanced in the
positive and negative directions.

10. The unitary structure of claim 9,
wherein said fiber material covering said core
comprises braided or wound continuous filament tow and
wherein the braid or winding angles are between about ±
45 degrees ± 15 degrees relative to the tangent of the
longitudinal axis through the centroid of the core.

11. The unitary composite article of claim 6, wherein said fiber material are carbon fibers said
resin material is epoxy resin.

12. In an external fixation device for
immobilizing a bone fracture that includes a plurality
of external fixation rings, a plurality of pins
anchored to the bone and clamped to the fixation rings
and lockable adjustment rods interconnecting the
fixation rings, the improvement comprising said fixation rings being a unitary composite structure that includes a core of a resin matrix reinforced with fibers, a fiber material covering said core and a resin impregnating said fiber material.